Plasma Skin Regeneration Technology Provides Unique Treatment Spectrum

By Bob Kronemyer, Associate Editor

Plasma Skin Regeneration (PSR) from Rhytec, Inc. (formerly Gyrus PLC) is not light-based (laser or IPL) or radiofrequency (RF). Rather, energy is delivered via plasma. Richard Fitzpatrick, M.D. of Dermatology Associates in Encinitas, Calif. and the UCSD School of Medicine was the first to use PSR in preclinical and clinical studies. "PSR intrigued me, as it applies a novel use of plasma energy. Plasma is the fourth state of matter in which electrons are stripped from atoms to form ionized gas," said Dr. Fitzpatrick. "With PSR, plasma is formed in nitrogen, activated by high power, ultra high frequency energy, which takes place within the handpiece. It is unlike any previous technology used before in cosmetic dermatology. Upon formation, the PSR plasma is directed through a quartz nozzle held 5 mm from the skin's surface, delivering energy in

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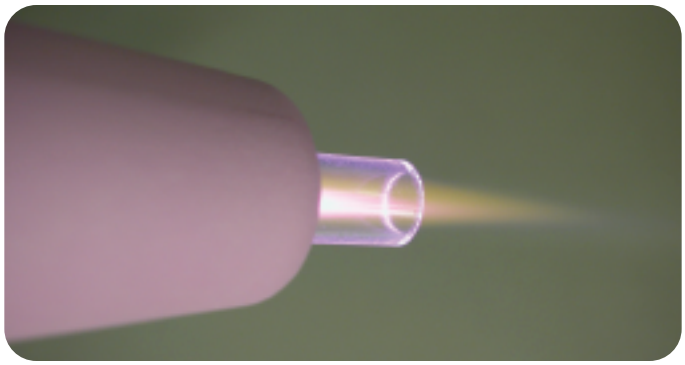
a 6 mm spot. Upon impact, ionized energy is released, causing a localized, instantaneous heating in a controlled, uniform manner without relying on a chromophore mediator."

PSR plasma generation is pulsed so that a known amount of energy is delivered, with predictable tissue effects and skin regeneration. Dr. Fitzpatrick added, "We can vary the depth of effect, from superficial epidermal to deeper dermal treatment similar to CO_2, but without vaporization of tissue or wiping between passes. Users can adjust the energy from 1 - 4 J per pulse delivered like an airbrush, without contact, applying a series of non-overlapping pulses."

With no target chromophore, the energy is evenly distributed irrespective of skin type. Treatment is performed under topical anesthesia; for higher fluence settings, adjunctive oral analgesia is suggested. Unlike CO_2 or Er:YAG lasers, investigators say PSR does not produce an explosive effect on tissue.

A preclinical study comparing PSR with the CO_2 laser was performed by Dr. Fitzpatrick in which treatment was delivered over a range of fluences. Biopsies taken were analyzed by Eric Bernstein, M.D., clinical associate professor, department of dermatology, University of Pennsylvania. Dr. Bernstein reported, "Of interest is the increased rate of healing at lower fluence settings. In addition, significant inflammation can be seen even with low fluences, possibly indicating the ability to produce significant clinical effect with quick healing time. Future studies on sun damaged facial skin will allow evaluation of the extent of this clinical effect and correlate it with the rapidity of healing. This treatment is a different modality than laser, and thus may have much different clinical results."



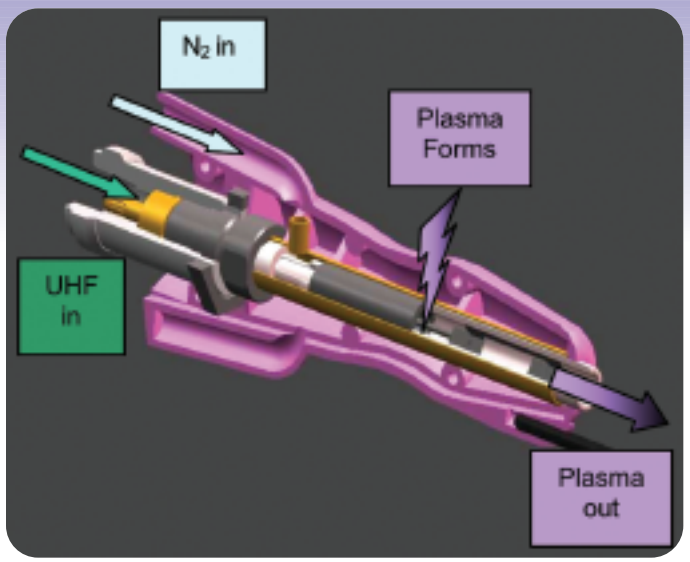
Plasma emanating from the PSR handpiece through the quartz nozzle.

Following animal studies, clinical studies were conducted at four U.S. sites under IRB approval by Dr. Fitzpatrick; Ronald Moy, M.D. and Jean-François Tremblay, M.D. of Moy Dermatology and UCLA; Roy Geronemus, M.D. of the Laser & Skin Surgery Center of New York; and Suzanne Kilmer, M.D. of the Laser & Skin Surgery Center of Northern California. The clinical studies included: assessment of collagen remodel-

Day 0: Before Tx

Day 90: After Tx

Photos courtesy of Suzanne Kilmer, M.D.



Pulsed N_2 and ultra high frequency (UHF) energy combine to form plasma in the handpiece. Plasma is directed onto skin surface without contact.

ing and contraction in post-auricular skin; perioral and periorbital treatments across the full range of fluences; and full face treatments at high and low fluences. The high fluence full face study was performed to identify the level of improvement associated with the single pass ablative energy. The low fluence full face study was performed to identify the level of improvement using a single pass, multi-treatment protocol at three week intervals with non-ablative energy levels.

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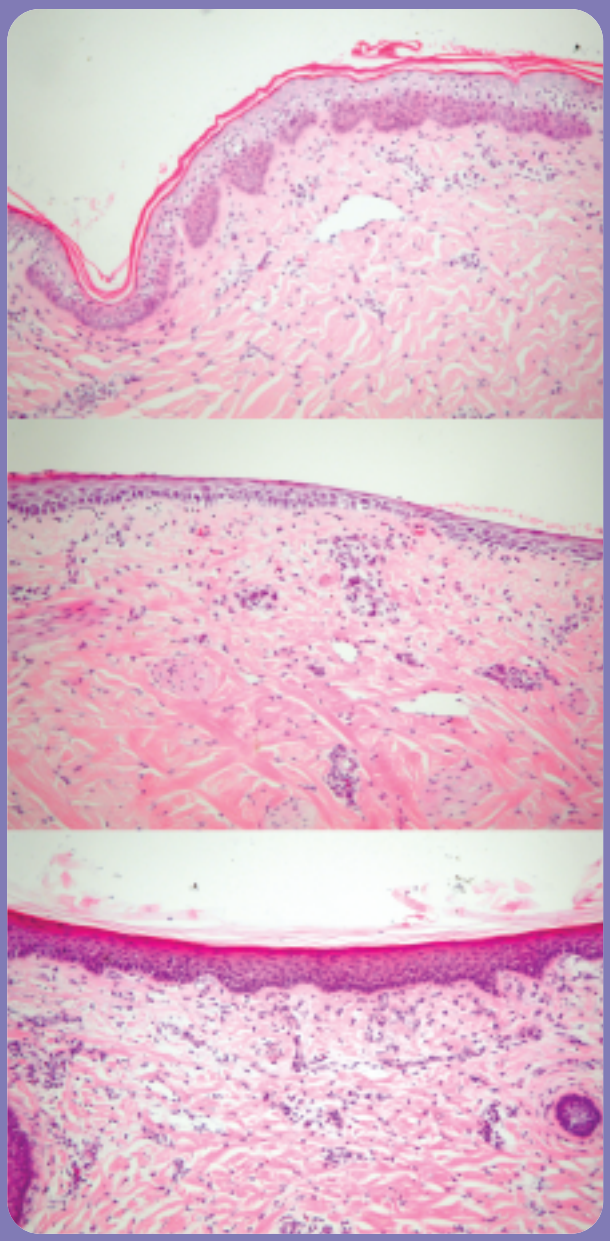
Dr. Kilmer reviewed the preclinical work and noted that the histology "showed uniform intact stratum corneum and epidermis immediately post-procedure and during early days following treatment. PSR appears to create a natural, intact and uninterrupted biological dressing that sheds naturally as new stratum corneum and epidermis are regenerated. If this is the case clinically, the patient's own protective dressing could retain growth factors, accelerate healing, and diminish the chance of scarring."

Dr. Kilmer's hypothesis was confirmed during her participation in a two site clinical study with Dr. Fitzpatrick using high fluence for treating the full face. "Immediately following treatment, patients fully retained their outer layers and recovery was much faster," she reported. Patients developed erythema and edema, but had no immediate evidence of epidermal loss or charring. Desquamation of the treated epidermis appeared within 48 hours, followed by epidermal recovery in seven days. Patients showed clinical improvement at 30 and 90 days and histology showed well-defined neocollagenesis. Patients reported a mean improvement of 50% at 90 days with further improvement seen at six months, consistent with continuing regenerative collagen remodeling.



Day 0 (top): Immediate PSR post-treatment with intact stratum corneum and epidermis. Day 2 (middle): Shedding of stratum corneum and new epidermal growth. Day 7 (bottom): New stratum corneum and regenerating epidermis; intact dermis.

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Drs. Moy and Tremblay conducted clinical studies on post-auricular skin prior to treating periorbital rhytides and evaluating repeat full face low fluence treatments. From these studies, Dr. Tremblay reported, "PSR is an exciting new device that allows for both ablative and non-ablative treatment of facial photodamage. With PSR, you can rapidly and safely treat a full face in less than ten minutes. Treatment of periorbital wrinkles showed results similar to the CO_2 laser with significantly shorter recovery time and absence of prolonged erythema and post-inflammatory dyspigmentation. Repeated low fluence treatments resulted in significant improvement in actinic dyspigmentation and skin texture with only two to four treatments at three week intervals." Repeated low fluence treatments conducted at both Moy's and Fitzpatrick's sites

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yielded a mean improvement of 44% at 90 days with a minimum of three ten minute treatments. Dr. Moy stated, "We were very impressed with the clinical safety profile of the PSR technology and outcome of our patient studies. Based on our results we decided to make PSR the treatment of choice for patients seeking cosmetic improvement of tone, texture, dyschromia, and reduction of wrinkles in photodamaged skin."

A consistent, remarkable feature of PSR technology is the depth of dermal response that can be achieved even at non-ablative fluences. Eliminating an intermediate chromophore to effect conversion of light-based energy into thermal energy provides a more efficient and uniform transfer of energy to tissues.

Day 0: Before Tx

Day 90: After Tx

Photos courtesy of Suzanne Kilmer, M.D.

Day 0: Perioral immediate post Tx

Day 30: Perioral after Tx

Photos courtesy of Richard Fitzpatrick, M.D.

Roy Geronemus, M.D. performed a two site, single treatment study with Dr. Fitzpatrick for treating perioral rhytides using low and high fluences. "There was a clinical and histological response based on the energies delivered. There was mild improvement with lower energies and more dramatic changes, and greater evidence of neocollagenesis at higher energies, primarily in the area underlying the dermal/epidermal junction. Erythema was minimal and increased slightly with increasing fluences. Epidermal recovery was three to four days at low fluences; four to seven days at high fluences. Treatment time took only a few minutes."

Analyzing the results of a single PSR treatment for photodamage at lower fluences – minimal erythema and mild clinical response – led to the additional study of repeat low fluence treatments on full faces at three week intervals by Drs. Fitzpatrick and Moy. Dr. Geronemus commented, "Although there is a tremendous number of non-ablative, rejuvenation treatments performed daily, a large segment of patients are looking for a more sustainable outcome following treatment for photodamage and wrinkles but are concerned about downtime and the complication rate of ablative laser resurfacing. It appears that the outcomes and safety profile of the PSR technology may fill this need in the market." ■

Editor's Note: PSR is FDA approved for the treatment of superficial skin lesions. Clinical studies have been completed to support an application to the FDA for perioral, periorbital, and full face low and high fluence treatment of wrinkles and photodamage.